باوزير فارما للاستشارات

Bawazir Pharma Consulting

Basic of Good Manufacturing Practice (GMP) SFDA Explained

Date of The Training

13 March 2023

Riyadh, Saudi Arabia

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KEY TOPICS

- GMP Legal Framework
- Type of GMP Inspection
- Quality Management
- Personnel
- Premises and Equipment
- Documentation
- Production
- Quality Control
- Contract Manufacture and Analysis
- Complaints and Product Recall
- Self Inspection

OVERVIEW

Understanding basics of GMP are essential skills for people working in pharmaceutical industry. This course will provide an explanation to SFDA GMP guidelines and how to prepare for inspection. This training will also enhance understanding and be beneficial to persons who work in scientific offices, regulatory affairs, pharmaceutical manufacturers, data management, basic research, project management and marketing, etc.

LEARNING OBJECTIVES

At the conclusion of this training, participants will be able to:

- Understand the principals of SFDA GMP guidelines.
- Describe the different types of GMP inspection.
- Understand The general GMP inspection components

WHO WILL ATTEND

Professionals working in:

- Pharma Regulatory Affairs
- Fresh Graduate
- Scientific Office Managers
- Regulatory Authorities.
- pharmaceutical manufacturers
- Pharmacist
- CRO staff

Bawazir Pharma Approach

Bawazir Pharma approach is grounded in the belief that compliance and quality should be managed as any other critical business issue. Proper quality management and a state of regulatory compliance will result in a decrease in direct costs such as rejects, and indirect costs such as adverse events and recalls.

Bawazir Pharma offers professional services to complete all aspects of regulatory affairs. The depth of our experience and knowledge acquired from our work with the Regulatory authorities ,ICH, International Standards Organization is made available to our partners. Our team can guide your organization through compilation of an original submission, perform submission maintenance and step in to support your internal staff during workload peaks.

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TRAINING PROGRAM

08:45 – 09:00 REGESTRATION and COFFEE

09:00 – 10:30 SESSION 1

GMP Legal Framework and type of GMP inspection

- Guide to Good Manufacturing Practice for Medicinal Products
- Good Storage and Distribution Practice (GSDP)
- Overview of Saudi GMP inspection

10:30 – 11:00: COFFEE BREAK

11:00 – 11:40 SESSION 2 :

Quality Management

- Quality Management Principle
- Quality Assurance
- Quality Control
- Product Quality Review
- Quality Risk Management
- Self Inspection

12:30 -13:30 LUNCH

13:30 – 14:40 SESSION 4:

Personnel, Premises, Equipment and Materials

- Personnel
- Principle
- General
- Key Personnel
- Training
- Personal Hygiene

15:30 – 16:00: COFFEE BREAK

16:00 – 16:30 SESSION 6

Documentation

- Documents Required
- Manufacturing Formula And Processing Instructions
- Packaging Instructions
- Batch Processing Records
- Batch Packaging Records
- Procedures And Records

PROGRAM OF DAY

11:40 – 11:45 : BREAK

11:45 – 12:30 SESSION 3

Production

- Prevention Of Cross-contamination In Production
- Validation
- Starting Materials
- Processing Operations - Intermediate And Bulk Products
- Packaging Materials
- Packaging Operations
- Finished Products
- Rejected, Recovered And Returned Materials

14:40 -14:45 BREAK

14:45 – 15:30 SESSION 5

Complaints, Product Recall ,Contract Manufacture and Analysis

- Principle
- Complaints
- Recalls
- The Contract Giver and the Contract Acceptor

16:30 – 17:00 SESSION 7

Quality Control

- Good Quality Control Laboratory Practice
- Documentation
- Sampling
- Testing
- On-going Stability Program

17:30 END OF TRAINING

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Bawazir Pharma Consulting

REGESTRATION

REGISTRATION FEES

Registration fee including refreshment breaks and lunches and training course material

FEES	SAUDI RIYAL
ADMISSION FEES	SAR 2000.00
EARLY BIRDS REGISTRATION FEE **PAY YOUR FEE BEFORE 12 March 2023**	**SAR 1000.00**

Payment can be made by Card or Bank Transfer

Name : Saleh Abdullah Bawazir Pharma Consulting Center
مركز صالح عبدالله باوزير للاستشارات المهنية

IBAN : SA69-0500-0068-2026-1725-5000

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To confirm your registration please send your payment receipt with your full name to info@bawazirpharma.com

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- SAR 1000.00
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EXPERT TRAINER

Prof. Saleh A Bawazir

CEO, Bawazir Pharma Consulting Center
EX-Vice President for Drug Sector (SFDA)

Professor Bawazir worked as vice president for drug affairs and advisor at the SFDA. During his work, he led the drug sector development through a strategic plan and managed to establish a state of the art drug regulatory system that ensure quality, safety and efficacy of the pharmaceutical products and contributed positively to overall public health. Under professor Bawazir supervision the SFDA built many electronic databases and regulatory framework that implement electronic Common Technical Document (eCTD) for drug submissions. Furthermore, Professor Bawazir represented the GCC for eight years in the Global Cooperation Group under the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

Eng. Sunil Nair FIE

Quality Operation Consultant,
Bawazir Pharma Consulting Center

Eng. Sunil Nair a pharmaceutical Engineer with Extensive Technical and Knowledge Management experience of about 3 decades. Experience with Pharmaceutical, Cosmeceutical, Nutraceutical and Food industry.

He has been instrumental in setting up an independent quality and regulatory compliance framework meeting global GMP standards like USFDA,TGA and MHRA.

He was Head Validation at SPIMACO for more than 8 years before joining Bawazir Pharma Consulting Centre.

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